UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,200	01/23/2001	Ernst Peter Rieber	028622/0103	1983

22428 7590 12/15/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,200	RIEBER, ERNST PETER	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 May 2002 and 12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47 and 53-57* is/are pending in the application.

4a) Of the above claim(s) *7,12-15,18-47 and 53-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6,8-11,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. As set forth previously, Applicant's election with traverse, of Group I, in Paper No. 10, filed 5/20/02, is acknowledged. Also, as set forth previously, Applicant is advised that Groups I and II have been rejoined. Applicant's election with traverse of the species "the antibody produced by the hybridoma DSM ACC2241", filed 9/12/03, is also acknowledged.

Applicant argues that, "the referenced portion of WO93/04187 does not disclose that the antibody, MRC OX-62, does not react with PBMCs, as is required by the claims."

Applicant is advised that the reference teaches a monoclonal antibody (mAb)that binds dendritic cells (DCs) at page 2 and further teaches that "All cells labeled with the OX-62 mAb had a dendritic cell morphology" at page 26. Accordingly, the antibody of the reference meets the limitations of Claim 1 because it would bind no other PBMCs except DCs.

Applicant further argues that "Pursuant to MPEP § 1850, in PCT national phase cases, (§371 cases) the Examiner is required to follow the determination of the International Bureau and cannot *sua sponte*, set forth his or her own groupings for purposes of examination. For example, *Caterpillar Tractor Co. v Commissioner of Patents*, 650 F.supp. 218, 231 USPQ 590 (VA 1986)."

Applicant is advised that if restriction is proper it is within the Examiner's power to restrict. Regarding *Caterpillar Tractor Co. v Commissioner of Patents*, the issue at hand was the Office's definition of an apparatus "specifically designed" for carrying out a process; the issue was not the Examiner's ability to restrict 371 applications in general as Applicant's assertions would imply.

Applicant argues that the examination of additional kit, polypeptide and polynucleotide claims would not place an undue burden on the Examiner.

Applicant is advised that undue burden is not a consideration in the restriction of applications filed under §371.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-15, 18-47, and 53-57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claim 7 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 1-6, 8-11 and 16-17 read on the elected invention and are being acted upon.

3. The specification is objected to for the following informalities:

A) The first line of the specification must include all priority data.

B) The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. See, for example, page 47 of the specification. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

4. The Abstract is objected to because it exceeds the maximum allowed length.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6, 8-11 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In Claims 1 and 17", the recitation of the phrases "reacts with an epitope", "DCs displaying features of", and "does not react with", are vague and indefinite as these comprise unscientific terms for which the precise limitations cannot be known. Additionally, it is unclear why such language would be used when scientifically-accepted terms, e.g., an antibody which binds an epitope, are well-known.

B) In Claim 2, the recitation of "wherein the DCs represent a DC population of a maturational stage between immature and mature DCs", is vague and indefinite as it is unclear what "represents" means and the metes and bounds of "a maturational stage between immature" are undefined.

C) In Claim 5, the recitation of "DCS of a restricted size and granularity", is vague and indefinite as these comprise terms for which the precise limitations cannot be known.

D) In Claims 8 and 16, the recitation of "DCs are recognized by the antibody" ("recognizing" in Claim 16) is vague and indefinite as "recognize" comprises an unscientific term for which the precise limitations cannot be known.

E) In Claim 10, the recitation of "a continuous cell line" is vague and indefinite as it is unclear what differentiates a "continuous" cell line from other cell lines.

F) The claims comprise incomplete sentences. Applicant is advised that the claims page should begin with "WE CLAIM" rather than "CLAIMS" such that when combined with the claims the combination comprises what can be considered a sentence, e.g., "we claim a method..." rather than "claims an antibody...".

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8, 9, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma DSM ACC2241 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. While it is noted in the specification that the hybridoma has been deposited under the provisions of the Budapest Treaty, Applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Applicant's provision of these assurances through the submission of an appropriate declaration would obviate this rejection.

9. Claims 6, 8-9, and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at

the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the "an antibody fragment of derivative thereof", recited in the claims. Said fragments comprise a potentially unlimited genus, however, no such fragments are disclosed. Accordingly, one of skill in the art would conclude that the specification fails to adequately describe the "fragment of derivative thereof" required for use in the claimed method. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 1, 6, 10, and 16-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 93/04187 (of record).

WO 93/04187 teaches a monoclonal antibody which reacts with DCs and not other PBMCs, a continuous stable cell line (a hybridoma), and a method for preparing said antibody (see particularly pages 2, 20, and 26).

The reference clearly anticipates the claimed invention.

12. Claims 1, 3, 4, 6, 10, and 16-17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent No. 5,766,570.

The '570 patent teaches a monoclonal antibody which reacts with DCs and not other PBMCs, a continuous stable cell line (a hybridoma), and a method for preparing said antibody (see particularly column 15, Production of monoclonal antibodies reactive with HB15). Note, HB15 is another name for CD83, a cell surface marker on mature DCs. Mature DCs are well-known to express HLA-DR, CD11c, and CD33 (see for example, Zhou et al., 1995, IDS).

The reference clearly anticipates the claimed invention.

13. No claim is allowed.

14. The antibody produced by hybridoma DSM ACC2241 appears to be free of the prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

12/10/03

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600